individual, partnership, corporation, or other entity required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter.

[56 FR 36089, July 31, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 59 FR 48959, Sept. 23, 1994; 60 FR 48373, Sept. 19, 1995; 66 FR 55790, Nov. 2, 2001]

§21.3 Definitions.

As used in this part:

Basic component. (1)(i) When applied to nuclear power plants licensed pursuant to 10 CFR part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1), §50.67(b)(2), or §100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR part 50, appendix B, or commercial grade items which have successfully completed the dedication process.

(2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Commercial grade item. (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Constructing or *construction* means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR part 50, dedicating entity means the organization that performs the dedication process. Dedication may

be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to §21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Defect means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in this section; or

(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to part 50 of this chapter.

Deviation means a departure from the technical requirements included in a procurement document.

Director means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, *director* means the individual.

Discovery means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in §21.21(a).

Evaluation means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

Notification means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

Operating or operation means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

Procurement document means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Responsible officer means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is

vested with executive authority over activities subject to this part.

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter.

Supplying or *supplies* means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

[42 FR 28893, June 6, 1977; 42 FR 36803, July 18, 1977, as amended at 43 FR 48622, Oct. 19, 1978; 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 56 FR 36089, July 31, 1991; 59 FR 5519, Feb. 7, 1994; 60 FR 48373, Sept. 19, 1995; 61 FR 65171, Dec. 11, 1996; 64 FR 72000, Dec. 23, 1999; 66 FR 55790, Nov. 2, 2001]

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent either by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/eie.html*, by calling (301) 415–6030, by e-mail to *EIE@nrc.gov*, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

[68 FR 58802, Oct. 10, 2003]

§ 21.6 Posting requirements.

(a)(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of—

(i) The regulations in this part;

(ii) Section 206 of the Energy Reorganization Act of 1974; and

(iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) The effective date of this section has been deferred until January 6, 1978.

[42 FR 28893, June 6, 1977, as amended at 60 FR 48374, Sept. 19, 1995]

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Suppliers of commercial grade items are exempt from the provisions of this part to the